**IN THE UNITED STATES DISTRICT COURT**

**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| UNITED STATES ex rel. YOASH GOHIL, | : | |
| Plaintiff/Relator. | : | CIVIL ACTION |
| | : | No. 02-2964 |
| v. | : | |
| | : | |
| SANOFI U.S. SERVICES INC. et al., | : | |
| Defendants. | : | |

**November 12, 2020** **Anita B. Brody, J.**

**MEMORANDUM**

## I. INTRODUCTION

This memorandum addresses Act Two of the two-act motions for summary judgment.

Plaintiff-Relator Yoash Gohil brings this lawsuit against his former employer, the pharmaceutical company Aventis.[1] Gohil contends that Aventis violated the False Claims Act ("FCA"). He claims that from 1996 to 2004, Aventis engaged in a nationwide marketing scheme involving a variety of kickbacks that induced doctors to prescribe the cancer drug Taxotere—prescriptions which the doctors then asked the government to reimburse.[2]

In Act One of the summary judgment motions, which I addressed on March 4, 2020, I denied cross-motions for summary judgment that specifically addressed Gohil's claims that Aventis's so-called reimbursement-assistance program—the "Providing Access to Cancer Therapy Program" or "PACT Program"—violated the FCA. *See* Order, Mar. 4, 2020, ECF No. 373; Mem., July 21, 2020, ECF No. 415 ("PACT Summ. J. Mem."). On April 20, 2020, in Act Two of the summary judgment motions, Aventis filed a summary judgment motion on the remaining schemes.[3] The remaining schemes are:

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[1] As a result of several mergers, the Defendant has gone by several different names throughout the relevant period of this lawsuit. For ease of reference, I refer to the Defendant solely as "Aventis."

[2] In what may have been a second scene of Act Two, Gohil alleged that Aventis engaged in false advertising to increase off-label prescriptions of Taxotere. Third Am. Compl. ¶¶ 20-115, ECF No. 134. Aventis moved for summary judgment on this claim. Mem. of Law in Supp. of Def.'s Mot. for Summ. J. 26-28, ECF No. 396. Gohil responded that "Aventis' false statements about off-label safety and efficacy of Taxotere are relevant to Relator's claims under 31 U.S.C. § 3729(a)(2) [the FCA] . . . ." Surreply in Opp'n to Def.'s Mot. for Summ. J. 2 n.1, ECF No. 409. But other than this conclusory statement, Gohil made no legal argument about *how* the false advertising resulted in FCA liability. *See* Mem. of Law in Opp'n to Def.'s Mot. for Summ. J. 25, ECF No. 404-2 ("Relator's claims are . . . based on evidence: (i) that Aventis caused doctors and hospitals to make false statements that there were no *kickbacks* . . . ; and (ii) that Aventis caused doctors to falsely *certify compliance with the [AKS]* . . . ." (emphasis added)).

Because Gohil inadequately discussed this claim, I will not address it and will grant summary judgment on the false advertising claim.

[3] In his Third Amended Complaint, Gohil did not organize his allegations by kickback scheme. On July 28, 2020, I identified the following alleged kickback schemes from the Third Amended Complaint: Advisory Boards, Speaker Programs, Education Grants, Preceptorships, and Ad Hoc Kickbacks. *See*

A. Advisory Boards;

B. Speaker Programs;

C. Education Grants;

D. Preceptorships; and

E. Ad Hoc Kickbacks.

This memorandum will address Act Two of the motions for summary judgment.

I will deny the motion as to the Advisory Boards, Speaker Programs, and Education Grants schemes. I will grant the motion as to the Preceptorships scheme. As for the Ad Hoc Kickbacks Scheme, I will deny the motion for the provision of meals and gift baskets, and I will grant the motion as to the remaining alleged ad hoc kickbacks.

## II. BACKGROUND[4]

Aventis's cancer drug, Taxotere, was first approved by the FDA in 1996. When it entered the market that year, Taxotere faced competitive disadvantages. Compared to its main competitor—a similar cancer drug called Taxol—Taxotere was more expensive and had been approved by the FDA for fewer specific uses. According to Gohil, Aventis aimed to overcome these disadvantages by pursuing an aggressive Taxotere marketing scheme from 1996 to 2004. As part of this marketing plan, Gohil contends that Aventis engaged in a number of kickback schemes to induce doctors to prescribe Taxotere instead of Taxol. I will describe each of the alleged schemes.

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Order 2, July 28, 2020, ECF No. 418 ("Causation Briefing Order"). Gohil was given a chance to dispute or supplement this characterization. *Id.* at 2 n.2. He did not. *See* Chart: Aventis' Kickback Schemes by Category Linked to Medicare Claims 1, ECF No. 427 ("Relator Causation Chart").

[4] The facts are presented in the light most favorable to Gohil, the nonmoving party. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). I use the ECF page numbers throughout to avoid confusion.

### A. Advisory Boards

On paper, Aventis implemented advisory boards to "create an intimate forum where oncology issues, clinical data, and patient care [could] be debated." Relator Ex. 53, at 19. In a presentation entitled "Maximizing Taxotere Growth," Vice President of Oncology Mark Alles described Aventis's advisory boards:

> Medical oncologists will be brought together to discuss issues important to their particular local area. There will be presentations from invited speakers. Participants will have the opportunity to comment on future clinical development plans, and existing data on Taxotere. Participants will also be asked their opinion on some marketing strategies.

*Id.* Aventis's internal compliance policies stated that advisory board attendees were to be chosen based on their qualifications—not their volume of business or favorable opinion of Taxotere—and compensated at fair market value. Aventis Ex. 54, at 2-3 ("Aventis 1997 Policies").

In practice, however, Aventis used advisory boards as a "sales tactic[]" to "expand Taxotere's market presence." Relator Ex. 41 pt. 2, at 1-2; Relator Ex. 44, at 334:22-335:9 ("Corrigan Dep. I"). Aventis paid doctors to attend advisory boards in desirable locations and offered valuable entertainment. Attendees received honoraria (around $1000) and all-expenses paid trips to locations like Rome and New York City. Relator Ex. 108; Relator Ex. 109. Aventis also organized entertainment for attendees, including golf outings and Broadway shows. Relator Ex. 24, at 191:2-22 ("Corrigan Dep. II"); Relator Ex. 109. To participate, attendees at advisory boards were required to sign acknowledgements that "these payments constitute[d] fair market value and [had] not been determined in a manner that [took] into account the volume or value of any referrals generated between the parties." Aventis 1997 Policies, at 50; Relator Ex. 108, at 3. But a spot check in 2004 revealed that Aventis only had signed agreements on file for two of the nine advisory board attendees audited. Relator Ex. 42 pt. 1, at 10.

Aventis invited "targeted physicians" from "key accounts" to attend advisory boards. Relator Ex. 41 pt. 2, at 2. For example, Vice President of Oncology Mark Alles applauded the invitation of a particular doctor to an advisory board: "Thanks for the favor on this one. I know it will pay-off big for us." Relator Ex. 64. Additionally, regional managers were advised to screen invitations to exclude "[p]hysicians who have strong potential to be antagonistic." Relator Ex. 58, at 4.

Furthermore, Aventis controlled the content of advisory boards. To assure doctors that they would "not be the first oncologist or lone wolf" to use Taxotere off-label, Aventis paid chosen doctors—or "thought leaders"—to deliver presentations about the benefits of off-label use. Corrigan Dep. II, at 187:5-21; Relator Ex. 58, at 3. Aventis ensured that "[e]ach speaker's slides were carefully reviewed prior to the meeting to make sure they covered all relevant topics." Relator Ex. 41 pt. 2, at 2. Senior Product Manager Gregg Bernier instructed regional directors and managers to further "maintain control" by eliminating Q & A and by "identify[ing] 'aces' in the audience" who could "shut-down the physicians who are being difficult." Relator Ex. 58, at 3. He explained: "We would like it to be clear Aventis is moderating the [advisory board], not the speakers. All moderators should use the attached slides. . . . Covering the market research slides will serve the following purpose: it will set the tone that this is a marketing meeting . . . ." *Id.* at 3-4.

**B. <u>Speaker Programs</u>**

On paper, Aventis set up what it characterized as speaker programs. In his "Maximizing Taxotere Growth" presentation, Vice President of Oncology Mark Alles described Aventis's "speakers bureau":

> A vendor maintains a registry of 300–500 national and regionally recognized experts in the field of Medical Oncology . . . . Physicians are trained on the latest

> Taxotere data during a 1–2 day seminar given 4 times each year. Updated information and slides are automatically forwarded to speakers under contract with [Aventis].

Relator Ex. 53, at 23. Aventis's internal compliance policies stated that speaker arrangements could not be based on the speaker's volume of business or favorable opinion of Taxotere and also required speakers to be compensated at fair market value. Aventis 1997 Policies, at 2-3.

In practice, Aventis targeted doctors from "key" accounts because "developing [doctors] as speakers and advocates had a positive impact on sales in the surrounding community territories." Relator Ex. 41 pt. 1, at 4, 11. As one regional manager explained: "by having young attending physicians from each of the major cancer centers[,] we will help strengthen long-term relationships between the account, the [doctor,] and Aventis Oncology. It will also . . . help generate referrals from the community." *Id.* at 11.

Aventis provided all-expenses paid trips, desirable entertainment, and honoraria to these select doctors. For 1999, Aventis budgeted $1.2 million for the speakers bureau and an additional $2 million for speaker training. Relator Ex. 53, at 23, 26. Using this budget, Aventis paid doctors to attend speaker "training" and "development" workshops in locations like Las Vegas. Relator Ex. 48. Proposals for workshops in "upscale resort[s]" in Grand Cayman Island and Key West budgeted $4465 and $5265 per doctor, respectively: this paid for a $1000 honorarium, two nights in a hotel, airfare and transportation, a welcome gift, meals, and a "social activity." Relator Ex. 49; Relator Ex. 50. The "social activit[ies]" involved valuable entertainment. A 1997 Area Manager Business Plan proposed that Aventis

> [i]nitiate creative programs to increase attendance at the local speaker programs (physicians are inundated with invitations due to the influx of new chemo agents last year) such as: speaker program followed by a golf outing with physicians[,] holding a speaker program at interesting venues such as the Del Mar Fairgrounds during horse racing season[,] a trip to the wine country in combination with a speaker program . . . .

Relator Ex. 54, at 6. Additionally, after speakers were trained, Aventis paid the speakers honoraria ranging from $500 to $2500 for each Taxotere-related speaking engagement they completed. Relator Ex. 190.

In exchange, Taxotere speakers completed minimal work. A 2000 report showed that the vast majority of speakers only completed one speaking engagement. *Id.* The most prolific speaker that year completed thirty-five engagements and was paid $70,000 in honoraria. *Id.*

The speaking engagements were used to market Taxotere. In an email forwarded to Aventis's sales team, a doctor invited to speak at a program entitled "Taxotere in the Management of Androgen-Independent (Hormone-Refractory) Metastatic Prostate Cancer" stated:

> I find it highly ethically questionable to approach academicians and community practioners [sic] to provide blatant marketing for a pharmaceutical product. One of our roles is to provide education on biology, diagnosis, and treatment of specific diseases and when that interest intersects with corporate interests to sell a product, a mutually beneficial agreement, open to public scrutiny, can be formed. I have nothing against Taxotere or Aventis, but putting the product name in the title and dictating content oversteps reasonable bounds and makes us all look bad—you hire sales people to do that work.

Relator Ex. 199.

### C. Education Grants

On paper, Aventis provided education grants to "support bona fide educational programs for patients, consumers, and/or health care professionals." Aventis Ex. 30D, at 31. Aventis's internal compliance guidelines stated that education grants could not be based on the recipient's volume of business. Aventis 1997 Policies, at 15-16.

In practice, Regional Sales Director Michael Fleming stated: "[T]he majority of grants should be limited to those accounts that we have access to and are using our products. I see an educational grant as a thank you for support and more for maintaining sales then [sic] increasing

them." Relator Ex. 63, at 17. Before approving a grant, Fleming told managers to consider factors including:

> How much money have we given to this account in the past year? How have sales been in the past year? How important is this account to our business? Why do we want to support this particular grant/program? What will we get from supporting this program/grant? How can we track our return on investment?

*Id.*

In an email, one doctor expressed disappointment at an Aventis Professional Oncology Education Manager's

> not so subtle desire to turn our meeting . . . into a 2 day sales pitch for [T]axotere. She has strongly suggested for us to invite only speakers from Aventis' speakers bureau, and has implied that future funding may be compromised if this isn't done. I am sure that this would not be the true intent for Aventis and is certainly not our objective. Such a biased (sales-oriented) meeting certainly would compromise our academic integrity and cheapen the position that Aventis has worked to attain in GU oncology.

Relator Ex. 90.

**D. <u>Preceptorships</u>**

On paper, preceptorships were an opportunity for Aventis sales representatives to "shadow a medical oncologist to learn more about how that oncologist treated cancer." Aventis Ex. 43, at 28:14-29:14. Aventis's internal compliance guidelines stated that promotional activities could not occur during preceptorships. Aventis Ex. 30D, at 47-48; Aventis 1997 Policies, at 54.

In practice, Aventis used preceptorships as another marketing opportunity. Area Manager Joe Baffone explained: "I know that every clinical, every preceptorship, I did in spending clinical time with medical oncologists, I had the opportunity to discuss, yes we're there to learn, but to discuss Taxotere, the use of Taxotere, to discuss individual patients and that's what its [sic] all about." Relator Ex. 33, at 21 (Ex. E). Aventis arranged preceptorships with low-prescribing

doctors. One area manager's business plan stated:

> Representatives will continue preceptorships with key offices—offering financial support if necessary, particularly if a "no-see" office. Area manager will coordinate a preceptorship program for physicians to attend at Cleveland Clinic or MDA (reserved for "no-see" and top priority physicians) so they can gain exposure to Taxotere, its ease of use, and lack of side effects in a very short period of time.

Relator Ex. 54, at 6.

**E. Ad Hoc Kickbacks**

On paper, Aventis implemented policies prohibiting gifts and business courtesies that were conditioned on purchasing or recommending Taxotere. Aventis 1997 Policies, at 25-29.

In practice, Aventis used a variety of ad hoc kickbacks to increase the number of Taxotere prescriptions. Sales representatives suggested offering "Gifts [for] attainment of certain volume business [and] gift certificates" as "promotional ideas." Relator Ex. 55 pt. 1, at 5. Specifically, Aventis sent gift baskets to doctors who were "Taxotere Speakers." Relator Ex. 188.

Sales representatives also took doctors out for meals as a "sales tactic[]" to "increase Taxotere usage." Relator Ex. 55 pt. 1, at 5; Relator Ex. 86, at 8, 11, 14. In a voicemail, Area Manager Joe Baffone praised Gohil and another sales representative after they "took a very important account of theirs out to dinner" because doing so "opens the doors for future access [and] gives us the ability to do the things that we need to do to impact the business." Relator Ex. 33, at 25 (Ex. F).

Additionally, to increase sales, sales representatives stated that they would "focus[] on what the individual desires are of each physician." Relator Ex. 86, at 7. Business plans included a variety of "sales tactics," such as "sporting events," "support of [an office's] annual holiday party," and trips to Dave & Buster's arcades. *See generally* Relator Ex. 55 pt. 1; Relator Ex. 86.

## III. STANDARD OF REVIEW

Summary judgment should be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is "material" if it "might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A factual dispute is "genuine" if the evidence would permit a reasonable jury to return a verdict for the nonmoving party. *Id.* In ruling on a motion for summary judgment, the court must draw all inferences from the facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

The moving party "always bears the initial responsibility of informing the district court of the basis for its motion." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). After the moving party has met its initial burden, the nonmoving party must then "make a showing sufficient to establish the existence of [every] element essential to that party's case, and on which that party will bear the burden of proof at trial." *Id.* at 322. Both parties must support their factual positions by: "(A) citing to particular parts of materials in the record . . . ; or (B) showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1). The materials in the record that parties may rely on include "depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials." *Id.* In opposing a motion for summary judgment, the nonmoving party may not "rely merely upon bare assertions, conclusory allegations or suspicions." *Fireman's Ins. Co. of Newark, N.J. v. DuFresne*, 676 F.2d 965, 969 (3d Cir. 1982).

In essence, the inquiry at summary judgment is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson*, 477 U.S. at 251-52.

## IV. THE LAW

Gohil asserts that each of Aventis's alleged schemes violated the False Claims Act ("FCA"). The FCA provides private citizens, called "relators," the ability to bring *qui tam* lawsuits on behalf of the government to recover civil damages against defendants who submit or cause the submission of "false or fraudulent claims" for payment from the government. Gohil brings FCA claims against Aventis under the FCA provisions that impose civil liability on anyone who "knowingly . . . causes to be presented . . . a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1), or who "knowingly . . . causes to be made or used, a false record or statement material to a false or fraudulent claim," *id.* § 3729(a)(2).[5] Specifically, Gohil alleges that Aventis's schemes caused doctors to submit "false or fraudulent claims" to the government for reimbursement for Taxotere.

To show that Aventis violated the FCA, Gohil must prove the following elements for each scheme: (1) falsity; (2) causation; (3) scienter; and (4) materiality. *United States ex rel. Petratos v. Genentech, Inc.*, 855 F.3d 481, 487 (3d Cir. 2017).

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[5] Congress amended the FCA in 2009 when it passed the Fraud Enforcement and Recovery Act ("FERA"). FERA slightly changed the FCA's codification: prior to 2009, these two sections were codified § 3729(a)(1) and § 3729(a)(2). After 2009, they are now codified as § 3729(a)(1)(A) and § 3729(a)(1)(B), respectively. To avoid confusion, I use only the pre-2009 codification.

For § 3729(a)(1), the pre-2009 version applies because all of the conduct in this case took place prior to 2009. For § 3729(a)(2), the post-2009 version applies because the FCA claims at issue in this case were pending after June 7, 2008. *See* PACT Summ. J. Mem. 15-16 n.13 (discussing which version of the FCA applies to Gohil's claims); *see also* Mem. Op. 21-22, Mar. 30, 2015, ECF No. 125 (Stengel, J.) (reaching the same conclusion in an opinion addressing Aventis's motion to dismiss Gohil's Second Amended Complaint).

**1. Falsity**

The first element of an FCA violation is falsity. There are two kinds of falsity that are actionable under the FCA: "factual falsity" and "legal falsity." *United States ex rel. Druding v. Care Alts., Inc.*, 952 F.3d 89, 96-97 (3d Cir. 2020). A claim is "factually false" when the claimant "misrepresents what goods or services that it provided to the Government." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011). A claim is "legally false" when the claimant misrepresents that he or she has complied with "statutory, regulatory, or contractual requirement[s]." *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 94 (3d Cir. 2018). In cases where the relator alleges that the defendant *caused* the submission of false claims rather than submitting the claims itself, legal falsity exists when the defendant "created and pursued a marketing scheme that it knew would, if successful, result in the submission by [others] of compliance certifications . . . that [the defendant] knew would be false." *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3d Cir. 2004).

Gohil advances only a "legal falsity" theory. For doctors to receive reimbursement for a claim under a federal health care program, they must certify that the claim complies with federal laws, including the AKS.[6] Gohil argues that Aventis pursued marketing schemes that violated

[6] During the relevant time period, doctors submitted claims using Form HCFA-1500, which included the following notice under the certification statement for Medicare: "Any one who misrepresents or falsifies essential information to receive payment from Federal funds requested by this form may upon conviction be subject to fine and imprisonment under applicable Federal laws." Health Care Fin. Admin., Dep't of Health & Hum. Servs., Form HCFA-1500, Health Care Insurance Claim Form (rev. 1990). For Medicaid, doctors were required to certify that they understood that "payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, m[ight] be prosecuted under applicable Federal or State laws." *Id.* Other Medicare and Medicaid certifications during the relevant time period explicitly mentioned kickbacks. *See, e.g., United States ex rel. Thompson v. Columbia/HCA Healthcare*, 20 F. Supp. 2d 1017, 1035 n.21 (S.D. Tex. 1998) (hospitals participating in Medicare and Medicaid had to acknowledge on Form HCFA-2552 that "if services identified by this report were provided or procured through the payment directly or indirectly of a kickback or [were] otherwise illegal, criminal, civil and administrative action, [fines], and/or imprisonment m[ight] result"; hospitals also had to certify compliance with "laws and regulations regarding the provision of health care services").

the AKS. Importantly, once a claim is tainted by an AKS violation, it is automatically legally "false" under the FCA.[7] *See Greenfield*, 880 F.3d at 95. Therefore, once a violation of the AKS has been established, the first element of the FCA, falsity, has been met.

The AKS is a criminal felony statute. The statute prohibits "knowingly and willfully" offering or paying any "remuneration" to induce prescriptions that may later be paid for under a federal health care program. 42 U.S.C. § 1320a-7b(b). Gohil claims that Aventis violated the AKS by paying doctors kickbacks to prescribe Taxotere, for which the doctors submitted claims for payment to the federal government. To establish that Aventis violated the AKS, Gohil must prove that (i) the alleged schemes involved offering or paying "remuneration"; (ii) at least one purpose of the schemes was to "induce" doctors to prescribe more Taxotere; and (iii) Aventis possessed the requisite scienter. *See id.*

***i. Remuneration***

For Gohil to prove that Aventis violated the AKS, he must first show that the scheme involved remuneration. The AKS defines "remuneration" to include "transfers of items or services for free or for other than fair market value." *Id.* § 1320a-7a(i)(6). Courts generally interpret the term "remuneration" "expansively to include anything of value in any form whatsoever." *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 805 (S.D.N.Y. 2017) (internal quotation marks omitted), *rev'd on other grounds*, 899 F.3d 163 (2d Cir. 2018). The Office of the Inspector General for the Department of Health and Human Services ("OIG") has issued guidance documents addressing interactions between pharmaceutical manufacturers

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[7] In 2010, Congress amended the AKS to provide that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). This amendment "clarified, but did not alter, existing law that claims for payment made pursuant to illegal kickbacks are false under the False Claims Act." *Greenfield*, 880 F.3d at 95 (internal quotation marks and brackets omitted).

and doctors. *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003) ("2003 OIG Guidance"); Off. of the Inspector Gen., Dep't of Health & Hum. Servs., *Special Fraud Alert: Prescription Drug Marketing Schemes* (1994), *reprinted in* HHS-OIG Special Fraud Alerts, 59 Fed. Reg. 65,372 (Dec. 19, 1994) ("1994 Special Fraud Alert"). Though these guidance documents are not binding, several courts have treated them as persuasive when evaluating whether specific schemes violate the AKS. *See, e.g., United States ex rel. Suarez v. AbbVie, Inc.*, No. 15 C 8928, 2019 WL 4749967, at *6 (N.D. Ill. Sept. 30, 2019); *United States ex rel. Forney v. Medtronic, Inc.*, No. 15-6264, 2017 WL 2653568, at *4 & n.2 (E.D. Pa. June 19, 2017).The guidance documents describe specific examples of "problematic relationships between manufacturers and physicians, including . . . consulting and advisory payments, . . . business courtesies and other gratuities, and educational and research activities." 2003 OIG Guidance, 68 Fed. Reg. at 23,738; *accord* 1994 Special Fraud Alert, 59 Fed. Reg. at 65,376.

***ii. "One Purpose to Induce"***

Next, for Gohil to prove that Aventis violated the AKS, he must show that at least one purpose of the remuneration was to induce prescriptions or referrals. *United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985). Gohil does not need to prove that this was the only purpose. *Id.*

***iii. AKS Scienter***

Last, for Gohil to prove that Aventis violated the AKS, he must show that Aventis acted "knowingly and willfully." 42 U.S.C. § 1320a-7b(b)(2). Gohil must show that Aventis "knew [that its] conduct was unlawful and intended to do something the law forbids." *United States v. Goldman*, 607 F. App'x 171, 174-75 (3d Cir. 2015).

As a threshold matter, the parties dispute the proper standard for imputing AKS scienter

to Aventis.[8] Aventis argues that Gohil must produce evidence to show either (1) the employees with the requisite scienter were at the "apex of power" such that their actions were "indistinguishable from those of the corporation" or (2) that senior management was aware that Aventis employees were engaged in unlawful conduct. *See United States v. Dynamics Rsch. Corp.*, No. 03cv11965, 2008 WL 886035, at *13 & n.26-16, *18-19 (D. Mass. Mar. 31, 2008). Gohil contends that he merely needs to show that the employees with the requisite scienter were acting within the scope of their employment or with apparent authority. *Id.*

The Third Circuit has instructed that "issues of knowledge and intent are particularly inappropriate for resolution by summary judgment." *Riehl v. Travelers Ins. Co.*, 772 F.2d 19, 24 (3d Cir. 1985). Regardless of which standard is used, the question of AKS scienter is one for the jury. *See id.*; Restatement (Second) of Agency § 228 cmt. d (Am. L. Inst. 1958) (stating that unless "the answer is clearly indicated," the jury must decide whether "the act done is so different from the act authorized that it is not within the scope of the employment").

Again, claims tainted by the AKS are automatically false under the FCA. *Greenfield*, 880 F.3d at 95. So, once Gohil proves a violation of the AKS, he satisfies falsity, the first element of the FCA.

**2. Causation**

The second element of an FCA violation is causation. Gohil must prove that Aventis caused "at least one" claim to be submitted to the federal government that "sought reimbursement for medical care that was provided in violation of the Anti-Kickback Statute." *Greenfield*, 880 F.3d at 98. Gohil may not simply describe the kickback scheme in the abstract: he must "link" that scheme to a "particular claim" submitted to the government for payment. *Id.*

[8] The parties appear to dispute the standard for imputing scienter for both the AKS and FCA. Their briefing, however, commingles the discussion of vicarious liability under the AKS and FCA.

at 98, 100. While Gohil does not need to prove a kickback "*actually* influenced a patient's or medical professional's judgment," he must show that a "particular patient [was] *exposed* to an illegal recommendation or referral and a provider submit[ed] a claim for reimbursement pertaining to that patient." *Id.* at 97, 100 (emphasis added).

**3. FCA Scienter**

The third element of an FCA violation is scienter. The FCA requires defendants to behave "knowingly." 31 U.S.C. § 3729(a)(1)–(2). The FCA defines "knowingly" to mean that a person "has actual knowledge of the information" in question or acts in "deliberate ignorance" or "reckless disregard of the truth or falsity of the information." *Id.* § 3729(b).[9] In legal falsity cases like this one, the FCA's scienter element essentially requires deliberate ignorance or reckless disregard of illegality. *See id.* The FCA's scienter element is easier to meet than the AKS's scienter element: the FCA only requires recklessness or deliberate ignorance of illegality, *id.*, while the AKS requires knowledge of illegality, *Goldman*, 607 F. App'x at 174-75.

Thus, a scheme that survives summary judgment on AKS scienter also survives summary judgment on FCA scienter.

**4. Materiality**

The fourth and final element of an FCA violation is materiality. The FCA requires that the alleged "misrepresentation about compliance with a statutory, regulatory, or contractual requirement . . . be material to the Government's payment decision." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016). "Material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or

[9] I use the pre-2009 codification of the FCA's definition of "knowingly." After 2009, the codification of this definition changed slightly, but its substance stayed the same.

property."[10] *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 761 (3d Cir. 2017) (internal quotation marks omitted). "Materiality look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Escobar*, 136 S. Ct. at 2002 (internal quotation marks omitted). "The materiality standard is demanding. The False Claims Act is not an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Id.* at 2003 (internal quotation marks and citations omitted).

In *Escobar*, the Supreme Court set out several nonexclusive factors to determine materiality: (i) whether compliance with a particular statute is a "condition of payment"; (ii) whether the violation is substantial and goes to "the essence of the bargain" or is "minor [and] insubstantial"; and (iii) whether the government pays or declines to pay a "particular claim" or "particular type of claim" when it has "actual knowledge that certain requirements were violated." *Id.* at 2003 & n.5-04; *see United States ex rel. Lutz v. Berkeley HeartLab, Inc.*, No. 9:14-230-RMG, 2017 WL 6015574, at *2 (D.S.C. Dec. 4, 2017) (summarizing the factors discussed in *Escobar*); *United States ex rel. Emanuele v. Medicor Assocs.*, 242 F. Supp. 3d 409, 431 (W.D. Pa. 2017) (same). Because the *Escobar* Court deemed these factors to be nonexclusive, courts may also consider other indications of materiality. *Escobar*, 136 S. Ct. at 2003-04; *United States ex rel. Escobar v. United Health Servs., Inc.*, 842 F.3d 103, 109 (1st Cir. 2016) ("[*Escobar*] makes clear that courts are to conduct a holistic approach to determining materiality . . . .").

Here, the parties agree on the meaning of materiality. They disagree, however, on

[10] In 2009, Congress amended the FCA to provide a uniform definition of materiality, which *Spay* quotes here. After 2009, this definition is now codified at 31 U.S.C. § 3729(b)(4). But the Third Circuit has made clear that the amendment "did not inject a new materiality standard into the FCA. Rather, the changes merely made explicit and consistent that which had previously been a judicially-imposed, and oftentimes conflicting, standard." *Spay*, 875 F.3d at 761. Thus, "the definition of 'material,' which is derived from the common law and was enshrined in the statute itself in 2009, has not changed." *Id.* at 763.

whether misrepresentations about the AKS are *per se* material under the FCA.

Some post-*Escobar* courts have held that misrepresentations about the AKS are *per se* material.[11] The Third Circuit has stated otherwise. In *Greenfield*, the Third Circuit explained that even if a relator proves an AKS violation—which satisfies the FCA's "falsity" element—"he must *also satisfy* the False Claims Act's materiality requirement, *as falsity and materiality are distinct requirements in this context*." 880 F.3d at 98 n.8 (emphasis added) (citing *Escobar*, 136 S. Ct. at 2002).

Thus, for materiality, there is only question before this Court at the summary judgment stage: whether a reasonable jury could find that the misrepresentations about the alleged AKS violations were material in this case.

## V. THE INDIVIDUAL SCHEMES

Again, to survive summary judgment, Gohil must show that each of his alleged schemes satisfies the FCA elements of (1) falsity (based on an AKS violation); (2) causation; (3) scienter; and (4) materiality. *See United States ex rel. Petratos*, 855 F.3d at 487. I analyze each alleged scheme in turn.

### A. Advisory Boards

Gohil has produced sufficient evidence to survive summary judgment on his claim that the Advisory Boards Scheme violated the FCA.

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[11] One line of cases found *per se* materiality because "no reasonable person could believe that AKS compliance is unimportant to the Government's reimbursement decisions." *E.g.*, *Lutz*, 2017 WL 6015574, at *2.

Another line of cases relied on Congress's 2010 amendment of the AKS, which provided that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). *See, e.g.*, *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019) (holding that the 2010 amendment "obviate[ed] the need for a plaintiff to plead materiality"). The 2010 amendment does not apply retroactively. *Wilkins*, 659 F.3d at 311 n.19. The alleged AKS violations in this case occurred before 2010. Gohil also filed this case before 2010. Thus, I will not address the effect of the 2010 amendment on the materiality standard.

Gohil alleges that Aventis used advisory boards as an opportunity to market Taxotere instead of allowing doctors to freely discuss "oncology issues, clinical data, and patient care." Relator Ex. 53, at 19. According to Gohil, Aventis carefully controlled the participants, speakers, and content of the advisory boards. Aventis disputes this characterization and asserts that the advisory boards were carried out according to its internal compliance guidelines as well as industry standards. Gohil has put forth sufficient evidence to create a genuine dispute of material fact as to each element of the FCA.

**1. Falsity**

Gohil has produced sufficient evidence to show falsity, the first element of an FCA violation. Gohil alleges that Aventis caused the submission of "legally false" claims because the claims were tainted by kickbacks. Claims that are tainted by kickbacks violate the AKS and are therefore automatically false. *Greenfield*, 880 F.3d at 94. To establish an AKS violation, Gohil must prove that (i) the advisory boards involved paying "remuneration"; (ii) at least one purpose of the advisory boards was to "induce" doctors to prescribe more Taxotere; and (iii) Aventis possessed AKS scienter. *See* 42 U.S.C. § 1320a-7b(b).

***i. Remuneration***

There is a genuine dispute of material fact about the first element of the AKS: whether the advisory boards involved paying "remuneration." Under the AKS, "remuneration" includes "transfers of items or services for free or for other than fair market value." 42 U.S.C. § 1320a-7a(i)(6). Courts interpret the term "expansively to include anything of value in any form whatsoever." *Wood*, 246 F. Supp. 3d at 805 (internal quotation marks omitted). The OIG's 1994 Special Fraud Alert—which is nonbinding but persuasive—stated that the AKS could be implicated by

> [a]ny prize, gift or cash payment, coupon or bonus (e.g., airline discounts and related travel premiums), offered to physicians and/or suppliers . . . in exchange for, or based on, prescribing or providing specific prescription products. These items are particularly suspect if based on value or volume of business generated for the drug company.

59 Fed. Reg. at 65,376. It specifically warned against offering "cash or other benefits to pharmacists (or others in a position to recommend prescription drug products) in exchange for performing marketing tasks . . . . [like] sales-oriented 'educational' or 'counseling' contacts . . . ." *Id.* The 2003 OIG Guidance further clarified: "In general, fair market value payments to small numbers of physicians for bona fide consulting or advisory services are unlikely to raise any significant concern. Compensating physicians as 'consultants' when they are expected to attend meetings or conferences primarily in a passive capacity is suspect." 68 Fed. Reg. at 23,738. Furthermore, "the use of health care professionals for marketing purposes—including, for example, ghost-written papers or speeches—implicates the anti-kickback statute." *Id.*

Aventis argues that the advisory boards did not involve paying remuneration because they were carried out in accordance with Aventis's internal compliance guidelines. Various versions of Aventis's guidelines required advisory board attendees to be compensated at fair market value and prohibited agreements with doctors that were conditioned on the amount of Taxotere prescribed by the doctors. *E.g.*, Aventis 1997 Policies, at 2-3. Furthermore, Aventis points to testimony by managers and declarations by advisory board attendees stating that Aventis did not control the content at advisory boards and that the advisory boards otherwise conformed to industry standards. Corrigan Dep. II, at 218:8-220:10; Aventis Ex. 6 ¶ 10.

But the evidence, viewed in the light most favorable to Gohil, suggests that Aventis did not follow its internal compliance guidelines. A reasonable jury could conclude that the Aventis's advisory boards involved paying "remuneration" because as part of the advisory

boards, Aventis offered "cash or other benefits" to those "in a position to recommend prescription drug products." *See* 1994 Special Fraud Alert, 59 Fed. Reg. at 65,376. Aventis provided advisory boards attendees with all-expenses paid trips to desirable destinations coupled with valuable entertainment. For example, in 2001, Aventis held a three-day "Docetaxel[12] in Lung Cancer Consortium" in Rome, Italy. Relator Ex. 108. On top of a $1000 honorarium, each attendee was provided three nights of hotel accommodations, a round-trip business class plane ticket (or two coach class tickets if he or she brought a guest), dinners, and "additional options for socializing and site seeing." *Id.* To participate, attendees were required to sign "Consultant Agreements," which stated that they were being compensated at fair market value. Relator Ex. 108, at 3; Aventis 1997 Policies, at 50. But a spot check in 2004 revealed that Aventis only had Consultant Agreements on file for two of the nine advisory board attendees audited. Relator Ex. 42 pt. 1, at 10.

Gohil has produced evidence suggesting that doctors attended advisory boards "primarily in a passive capacity" because Aventis carefully controlled the attendance and tone of the meetings. *See* 2003 OIG Guidance, 68 Fed. Reg. at 23,738. Aventis managers were advised to "screen" the invitation list for advisory boards because "physicians who have strong potential to be antagonistic should not be in attendance." Relator Ex. 58. Senior Product Manager Gregg Bernier instructed that, during the advisory boards, regional directors and managers should eliminate Q & A sessions to "maintain control." *Id.* Additionally, he told managers to "identify 'aces' in the audience" who could be used to "shut-down the physicians who are being difficult." *Id.*

Likewise, Gohil has produced evidence that Aventis used "health care professionals for

[12] Docetaxel is sold under the brand name Taxotere, among others.

marketing purposes" through "ghost-written" materials. *See* 2003 OIG Guidance, 68 Fed. Reg. at 23,738. In his 2002 Business Plan, Regional Director Michael Fleming explained that "[e]ach speaker's slides were carefully reviewed prior to the [advisory board] to make sure they covered all relevant topics." Relator Ex. 41 pt. 2, at 2. Furthermore, Senior Product Manager Gregg Bernier told regional directors:

> We would like it to be clear Aventis is moderating the [advisory board] meeting, not the speakers. All moderators should use the attached slides. . . . Allowing the moderator to set the expectations at the beginning of the meeting, sticking to the slides, and eliminating the Q & A will help us maintain control.

Relator Ex. 58. Thus, Gohil has raised a genuine dispute of material fact about whether the advisory boards involved paying remuneration.

***ii. "One Purpose to Induce"***

There is a genuine dispute of material fact about the second element of the AKS: whether one purpose of the advisory boards was to induce doctors to prescribe Taxotere. The AKS requires that at least one purpose of the remuneration was to induce prescriptions or referrals. *Greber*, 760 F.2d at 72. Gohil does not need to prove that this was the only purpose. *Id.*

Aventis argues that the advisory boards were FDA-sanctioned and industry-standard events for "oncologists to share knowledge and experience," "remain up-to-date on drug properties, benefits and side effects of drugs, and to review clinical trial results." Aventis Ex. 19, at 11. Aventis relies again on its internal compliance guidelines as well as testimony by its employees and by advisory board attendees. Aventis 1997 Policies, at 2-3; Corrigan Dep. II, at 218:8-220:10; Aventis Ex. 6 ¶ 10.

In response, Gohil has produced compelling evidence that at least one purpose of the advisory boards was to induce prescriptions to "expand Taxotere's market presence." Corrigan Dep. I, at 334:22-335:9. In an email to Aventis regional directors, Senior Product Manager

Gregg Bernier advised: "Covering the market research slides will serve the following purpose: it will set the tone that this [advisory board] is a marketing meeting . . . ." Relator Ex. 58, at 4. Likewise, Regional Director Michael Fleming analyzed advisory boards as a "sales tactic[]" and attributed the success of the tactic to focusing on "targeted physicians" and "attract[ing] a variety of physicians from our key accounts." Relator Ex. 41 pt. 2, at 1-2. Applauding the invitation of a particular doctor to an advisory board, Vice President of Oncology Mark Alles stated: "Thanks for the favor on this one. I know it will pay-off big for us." Relator Ex. 64. Thus, Gohil has raised a sufficient dispute as to whether one purpose of the advisory boards was to induce doctors to prescribe Taxotere.

***iii. AKS Scienter***

There is a genuine dispute of material fact about the third and final element of the AKS: whether Aventis possessed the requisite scienter. The AKS requires that a defendant act "knowingly and willfully." 42 U.S.C. § 1320a-7b(b)(2). Gohil must show that Aventis "knew [that its] conduct was unlawful and intended to do something the law forbids." *Goldman*, 607 F. App'x at 174-75. "[I]ssues of knowledge and intent are particularly inappropriate for resolution by summary judgment." *Riehl*, 772 F.2d at 24.

Aventis argues that it did not have AKS scienter because it enacted an internal compliance program for its advisory boards before any OIG guidance was issued and because the OIG guidance documents that were eventually issued largely mirrored the compliance policies that Aventis already enacted. *E.g.*, Aventis 1997 Policies.

But the evidence viewed in the light most favorable to Gohil suggests: As early as 1994, Aventis knew that its advisory boards implicated the AKS; Aventis's internal compliance guidelines confirmed this understanding. Aventis managers and employees ignored the

compliance guidelines about advisory boards. Aventis did not meaningfully discipline employees for violations of the compliance guidelines.

A reasonable jury could find that Aventis knew that its advisory boards were run in a manner that violated the AKS. In August 1994, the OIG warned that "investigation may be warranted" for

> [a]ny prize, gift or cash payment, coupon or bonus (e.g., airline discounts and related travel premiums), offered to physicians and/or suppliers . . . in exchange for, or based on, prescribing or providing specific prescription products. These items are particularly suspect if based on value or volume of business generated for the drug company.

1994 Special Fraud Alert, 59 Fed. Reg. at 65,376. Furthermore, the OIG stated that the AKS was potentially implicated by prescription drug marketing programs that offered "cash or other benefits to pharmacists (or others in a position to recommend prescription drug products) in exchange for performing marketing tasks in the course of pharmacy practice related to Medicare or Medicaid. The marketing tasks may include sales-oriented 'educational' or 'counseling' contacts, or physician and/or patient outreach, etc." *Id.* Similarly, the 2003 OIG Guidance advised that "[c]ompensating physicians as 'consultants' when they are expected to attend meetings or conferences primarily in a passive capacity is suspect." 68 Fed. Reg. at 23,738. It specifically stated that "the use of health care professionals for marketing purposes—including, for example, ghost-written papers or speeches—implicates the anti-kickback statute." *Id.*

A jury could find that Aventis's internal compliance guidelines demonstrated Aventis's understanding that its advisory boards violated the AKS. In Aventis's 1997 "Business Ethics Policies & Procedures," the section on "Consulting, Speaking and Other Fee for Service Arrangements" warned:

> Where the services to [Aventis] are being provided by individuals who either purchase or use [Aventis] products, or have influence over the purchase or use of

> [Aventis] products, special requirements must be met to assure compliance with relevant laws, such as the Federal Health Programs (including Medicaid and Medicare) anti-kickback statute, which affect [Aventis's] relationship with its customers and potential customers.

Aventis 1997 Policies, at 2. Under "Examples of Activities That Are Impermissible Under These Policy Requirements," the compliance guideline listed a "meeting with 'physician consultants' who are being paid as consultants but that consists primarily of an [Aventis] sales presentation." *Id.* at 3.

Gohil has produced evidence that Aventis managers and sales personnel ignored these compliance guidelines. Aventis managers received training on these policies, certified review of them, and were tasked with enforcing them. Aventis Ex. 38, at 3, 5. Sales personnel also received training and certified their review of the policies. Aventis Ex. 39. Though the guidelines prohibited meetings with consultants that consisted "primarily of an [Aventis] sales presentation," managers like Vice President of Oncology Mark Alles, Regional Director Michael Fleming, and Senior Product Manager Gregg Bernier encouraged employees to "maintain control" over the content and attendance of advisory boards and "set the tone that [an advisory board was] a marketing meeting." Aventis 1997 Policies, at 3; Relator Ex. 41 pt. 2, at 2; Relator Ex. 58; Relator Ex. 64.

Finally, Gohil has produced evidence that Aventis did not meaningfully discipline employees for violating its internal compliance guidelines. In 1996, seven employees were cited for infractions involving "[p]romotional practices; lack of attention during 1996 calendar year." Relator Ex. 103, at 2. The employees only had their infraction "[n]oted in 1996 year-end appraisal" and their "bonus reduced by 0.05 in performance adjustment factor." *Id.* When Area Manager Michael Corrigan violated Aventis's promotional policies, he received a written warning in 2002 that did not prevent him from receiving his full bonus, maintaining his position,

or being subsequently promoted. Corrigan Dep. II, at 344:6-345:4. Rather, Vice President of Oncology Mark Alles told Corrigan that Corrigan needed to accept the written warning because Alles "wanted to protect the brand to ensure that it was demonstrated that Aventis is a fully-compliant organization." *Id.* at 348:13-349:7. Likewise, Area Manager Joe Baffone was issued a final written warning in 2003 for violating Aventis's promotional policies. Relator Ex. 29, at Ex. 5. Though the stated consequences were "loss of payment of bonus for Q3 and Q4 of 2003, not eligible for contests, not eligible for promotion," Alles told Baffone that the consequences would "in no way, shape or form have an impact on [his] future." *Id.*; Relator Ex. 45, at 312:6-313:7. Thus, Gohil has raised a sufficient dispute about whether Aventis possessed AKS scienter.

As such, Gohil has provided sufficient evidence to support a jury finding in his favor for each element of the AKS. Because a reasonable jury could find that Aventis violated the AKS, Gohil has raised a genuine dispute of material fact as to falsity, the first element of the FCA.

**2. Causation**

Gohil has produced sufficient evidence to show causation, the second element of an FCA violation. Gohil must prove that Aventis caused "at least one" claim to be submitted to the federal government that "sought reimbursement for medical care that was provided in violation of the Anti-Kickback Statute." *Greenfield*, 880 F.3d at 98. Gohil may not simply describe the kickback scheme in the abstract: he must "link" that scheme to a "particular claim" submitted to the government for payment. *Id.* at 98, 100. While Gohil does not need to prove a kickback "*actually* influenced a patient's or medical professional's judgment," he must show that a "particular patient [was] *exposed* to an illegal recommendation or referral and a provider submit[ed] a claim for reimbursement pertaining to that patient." *Id.* at 97, 100 (emphasis added).

Gohil's causation evidence is based on the reports from two of his experts, Dr. Ian Larkin

and Dr. Meredith B. Rosenthal. Dr. Larkin's report reviewed empirical literature, which suggested that incentives like all-expenses paid seminars could influence doctors' prescribing behavior for up to two years after the incentive, even when the doctors themselves did not believe they had been influenced. Relator Ex. 97, at 12. To produce her report, Dr. Rosenthal relied on Dr. Larkin's conclusion that kickbacks could influence prescribing behavior for up to two years. Relator Ex. 47 ¶ 45 & n.59. Dr. Rosenthal's report identified the number of claims submitted by individual doctors within six months, one year, and two years of the alleged kickback event—here, attendance at an advisory board. *Id.* app. tbls.A10–A15. For example, Dr. Vician attended four Aventis advisory boards from March 16, 2002 to July 27, 2002. Relator Ex. 204. Dr. Rosenthal's report found that between March 16, 2002 and January 25, 2003 (six months after the last advisory board on July 27, 2002), Dr. Vician submitted 100 Medicare claims for Taxotere. Relator Ex. 47 app. tbl.A10, l. 53.

Aventis raises several arguments about why there is no genuine dispute regarding causation.

First, Gohil's causation evidence is based on Dr. Larkin's unsworn expert report, which Aventis argues is not competent to be considered as evidence at the summary judgment stage. "An affidavit or declaration used to support or oppose a [summary judgment] motion must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated." Fed. R. Civ. Pro. 56(c)(1)(A)(4). An unsworn expert report "is not competent to be considered on a motion for summary judgment." *Fowle v. C & C Cola*, 868 F.2d 59, 67 (3d Cir. 1989). But "evidence should not be excluded on summary judgment on hypertechnical grounds," especially when the error has since been corrected. *See id.* at 67. Gohil has cured the defect by submitting a sworn

declaration by Dr. Larkin. Relator Ex. 212. As such, Dr. Larkin's report may be considered as evidence.

Next, Aventis challenges Dr. Larkin's conclusions about the potential influence of Aventis's conduct on doctors' prescribing behavior. Aventis offers its own expert, Dr. Iain Cockburn. Aventis Ex. 14. This is a classic battle of the experts that renders summary judgment even more inappropriate: "[Gohil and Aventis's] expert opinions are in direct conflict with each other. To the extent the differing opinions must be reconciled, such a factual interpretation is within the province of a jury." *Rooney v. City of Philadelphia*, 623 F. Supp. 2d 644, 656 (E.D. Pa. 2009); *see also Lansford-Coaldale Joint Water Auth. v. Tonolli Corp.*, 4 F.3d 1209, 1216 (3d Cir. 1993) ("[I]n a battle of the experts, the factfinder 'decide[s] the victor.'" (quoting *Mendes-Silva v. United States*, 980 F.2d 1482, 1487 (D.C. Cir. 1993))).

Finally, Aventis argues that Gohil has only offered evidence of "temporal proximity," which is insufficient to show causation. Aventis relies on *Greenfield* to support its proposition. In *Greenfield*, the Third Circuit considered a kickback scheme involving Accredo, a pharmacy that provided home care to patients with hemophilia. *Id.* at 91. The *Greenfield* relator alleged the following causal chain: First, from 2007 to 2012, Accredo made charitable donations to Hemophilia Services, Inc. ("HSI") and Hemophilia Association of New Jersey ("HANJ"). *Id.* Second, in return for this alleged kickback, HANJ listed Accredo on its website as an HSI-approved vendor, reminded users to "work with our HSI [approved] providers," and highlighted that Accredo "continually contribute[d] to this community." *Id.* at 91-92. Third, twenty-four patients were allegedly "exposed to [HANJ's] illegal referral or recommendation" and subsequently used Accredo. *See id.* at 100. Fourth, from 2007 to 2012, Accredo submitted claims for those twenty-four federally insured patients. *Id.* at 93.

The Third Circuit held that the relator failed to show causation because he had no evidence to support the third link in his causal chain: that twenty-four patients had actually been exposed to HANJ's illegal recommendations or referrals. *Id.* at 99. The relator could not show that the twenty-four patients had viewed HANJ/HSI's list of approved providers or had been otherwise referred to Accredo by HANJ. *Id.* In fact, he could not even show that the twenty-four patients were members of HANJ or received HANJ communications. *Id.* Thus, all the relator could show was "temporal proximity"—that is, Accredo happened to be operating a kickback scheme during the same time period as it was submitting potentially unconnected federal claims. *Id.* at 100.

Here, Gohil's causal chain does not suffer the same fatal flaw. Gohil alleges the following causal chain: First, from 1996 to 2004, Aventis paid doctors to attend advisory boards about prescribing Taxotere. Second, in return for this alleged kickback, doctors prescribed Taxotere to their patients. Third, these patients were exposed to their doctors' illegal recommendation (the Taxotere prescription) and used Taxotere. Fourth, from 1996 to 2004, the doctors submitted federal claims for the Taxotere they prescribed to these patients. Unlike *Greenfield*, where there was no evidence that the patients who used Accredo were exposed to HANJ's illegal recommendations, here there is ample evidence to show that the patients who used Taxotere were exposed to the doctors' illegal recommendations: the doctors' prescription of Taxotere was the illegal recommendation.

Gohil has produced evidence to support each link of this causal chain. Relator Causation Chart 3. Gohil's expert, Dr. Larkin, states that incentives like all-expenses paid seminars can influence doctors' prescribing behavior for up to two years after the incentive. Relator Ex. 97, at 12. If Dr. Larkin's testimony is credited, a reasonable jury could conclude that a kickback like an

advisory board influences a doctor's decision to prescribe Taxotere for up to two years after the kickback. *See id.* So, claims that are submitted within that two-year window involve patients who were "exposed to an illegal recommendation or referral." *See Greenfield*, 880 F.3d at 100. For example, between March 16, 2002 and July 27, 2002, Aventis paid Dr. Vician to attend four advisory boards. Relator Ex. 204. Between March 16, 2002 and January 25, 2003 (six months after the last advisory board on July 27, 2002), Dr. Vician submitted 100 claims to Medicare for Taxotere. Relator Ex. 47 app. tbl.A10, l. 53. These 100 claims are evidence both that Dr. Vician actually prescribed Taxotere and that she submitted federal claims for those prescriptions. Because Dr. Vician prescribed Taxotere within two years of attending advisory boards—the window during which Gohil's expert opines that kickbacks influence prescribing behavior—a reasonable jury could find that the advisory boards caused Dr. Vician to prescribe Taxotere and, in turn, to submit federal claims. Thus, Gohil has created a genuine dispute of material fact regarding causation, the second element of the FCA.

**3. FCA Scienter**

Gohil has produced sufficient evidence to show scienter, the third element of an FCA violation. The FCA requires defendants to behave "knowingly." 31 U.S.C. § 3729(a)(1)–(2). The statute defines "knowingly" to mean that a person "has actual knowledge of the information" in question or acts in "deliberate ignorance" or "reckless disregard of the truth or falsity of the information." *Id.* § 3729(b). In legal falsity cases like this one, the FCA's scienter element essentially requires deliberate ignorance or reckless disregard of illegality. *See id.* The FCA's scienter element is easier to meet than the AKS's scienter element: the FCA only requires recklessness or deliberate ignorance of illegality, *id.*, while the AKS requires knowledge of illegality, *Goldman*, 607 F. App'x at 174-75. Because Gohil can survive summary judgment on

AKS scienter, he can also survive summary judgment on FCA scienter.

**4. Materiality**

Gohil has produced sufficient evidence to show materiality, the fourth and final element of an FCA violation. The FCA requires that the alleged "misrepresentation about compliance with a statutory, regulatory, or contractual requirement . . . be material to the Government's payment decision." *Escobar*, 136 S. Ct. at 1996. "Material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Spay*, 875 F.3d at 746 (internal quotation marks omitted). "Materiality look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Escobar*, 136 S. Ct. at 2002 (internal quotation marks omitted).

The parties point to various facts as probative of whether the misrepresentations about AKS violations were material in this case. Gohil argues that the AKS is a condition of payment under Medicare and that AKS violations are serious criminal felonies, punishable during the relevant time-period in this case by up to five years in prison. Aventis responds that the government paid claims for Taxotere despite knowing about Gohil's allegations of wrongdoing and that the government has declined to intervene in Gohil's case.

On these facts, it is a question for the jury whether the government would have paid for Taxotere had it known that Aventis was violating the AKS.[13] A reasonable jury could find that the alleged misrepresentations about the AKS satisfy materiality, the fourth and final element of the FCA.

Because Gohil has shown that a reasonable jury could find for him on each element of the FCA, I will deny summary judgment as to the Advisory Boards Scheme.

[13] Act One of these summary judgment motions provides an extensive discussion of the materiality of the misrepresentations in this case. *See* PACT Summ. J. Mem. 35-43.

**B. Speaker Programs**

Gohil has produced sufficient evidence to survive summary judgment on his claim that the Speaker Programs Scheme violated the FCA.

Gohil alleges that Aventis "develop[ed]" doctors to promote Taxotere: Aventis spent millions of dollars to provide doctors with all-expenses paid trips to speaker "training" and "development" programs in desirable locations in connection with valuable entertainment. Relator Ex. 41 pt. 1, at 4; Relator Ex. 48. Gohil asserts that most speakers completed minimal work in exchange for the lavish trainings and that Aventis paid some speakers tens of thousands in honoraria per year. Aventis argues that the speaker programs were carried out according to its internal guidelines as well as industry standards. Aventis also claims that speakers were compensated at fair market value for their activities.

Gohil can survive summary judgment on the Speaker Programs Scheme because he has raised a genuine dispute of material fact as to each element of the FCA: (1) falsity (based on an AKS violation); (2) causation; (3) scienter; and (4) materiality.

**1. Falsity**

Gohil has produced sufficient evidence to show falsity, the first element of an FCA violation. Gohil alleges that Aventis caused the submission of "legally false" claims because the claims were tainted by kickbacks. Claims that are tainted by kickbacks violate the AKS and are therefore automatically false. *Greenfield*, 880 F.3d at 94. To establish an AKS violation, Gohil must show (i) Aventis's speaker programs involved paying "remuneration"; (ii) at least one purpose of the speaker programs was to "induce" doctors to prescribe more Taxotere; and (iii) Aventis had the requisite scienter for the AKS. *See* 42 U.S.C. § 1320a-7b(b).

***i. Remuneration***

There is a genuine dispute of material fact about the first element of the AKS: whether the speaker programs involved paying "remuneration." A jury could find that the speaker programs involved "transfers of items or services for free or for other than fair market value." 42 U.S.C. § 1320a-7a(i)(6). The OIG's 1994 Special Fraud Alert warned that the AKS could be implicated when pharmaceutical companies "offer[ed] cash or other benefits to pharmacists (or others in a position to recommend prescription drug products) in exchange for performing marketing tasks in the course of pharmacy practice related to Medicare or Medicaid," including "sales-oriented 'educational' or 'counseling' contacts." 59 Fed. Reg. at 65,376. Likewise, the 2003 OIG Guidance stated: "[O]f concern are compensation relationships with physicians for services connected directly or indirectly to a manufacturer's marketing and sales activities, such as speaking . . . . In particular, the use of health care professionals for marketing purposes—including, for example, ghost-written papers or speeches—implicates the anti-kickback statute." 68 Fed. Reg. at 23,738.

Viewed in the light most favorable to Gohil, the speaker programs involved paying remuneration because they were "compensation relationships with physicians for services connected directly or indirectly to [Aventis's] marketing and sales activities." *See* 2003 OIG Guidance, 68 Fed. Reg. at 23,738. Aventis provided doctors all-expenses paid trips to attend speaker "training" and "development" programs in desirable locations like Las Vegas and offered valuable "social activit[ies]" to attendees. *E.g.*, Relator Ex. 48 (asking sales team members to submit nominations for doctors to attend a Taxotere "speaker training workshop" in Las Vegas); Relator Ex. 49 (proposing a "speaker development workshop" in Key West and budgeting $5265 per doctor, which included funding for a "social activity"); Relator Ex. 54, at 6 (proposing combining speaker programs with entertainment like golf outings and trips to wine

country). Additionally, Aventis paid doctors honoraria for attending the speaker "training" and "development" programs as well as for completing speaking engagements. *E.g.*, Relator Ex. 49 (proposing $1000 honoraria for attendees at a "speaker development workshop"); Relator Ex. 190 (documenting honoraria ranging from $500 to $2500 per speaking engagement). Though Aventis budgeted over $3 million to train and fund speakers in 1999, speakers were expected to complete minimal work: a review of Aventis-trained speakers in 2000 revealed that the vast majority of speakers only completed one speaking engagement. Ex. 53, at 23, 26; Relator Ex. 190. The same year, Aventis paid the most prolific speaker $70,000 in honoraria for completing thirty-five speaking engagements. Relator Ex. 190.

A reasonable jury could find that doctor-speakers engaged in "sales-oriented 'educational'" contacts because they were expected to recommend Taxotere to their peers during their speaking engagements. *See* 1994 Special Fraud Alert, 59 Fed. Reg. at 65,376. Aventis sent speakers "[u]pdated information and slides" about Taxotere. Relator Ex. 53, at 23. Regarding this practice, one doctor invited to speak at a program entitled "Taxotere in the Management of Androgen-Independent (Hormone-Refractory) Metastatic Prostate Cancer" stated:

> I find it highly ethically questionable to approach academicians and community practioners [sic] to provide blatant marketing for a pharmaceutical product. One of our roles is to provide education on biology, diagnosis, and treatment of specific diseases and when that interest intersects with corporate interests to sell a product, a mutually beneficial agreement, open to public scrutiny, can be formed. I have nothing against Taxotere or Aventis, but putting the product name in the title and dictating content oversteps reasonable bounds and makes us all look bad—you hire sales people to do that work.

Relator Ex. 199. As such, a reasonable jury could find that the speaker programs were remuneration under the AKS.

***ii. "One Purpose to Induce"***

There is a genuine dispute of material fact about the second element of the AKS: whether

one purpose of the speaker programs was to induce doctors to prescribe Taxotere. As one regional director explained in a 2002 business plan, "developing [doctors] as speakers and advocates had a positive impact on sales in the surrounding community territories." Relator Ex. 41 pt. 1, at 4. He further stated:

> We need to increase the number of Taxotere Speaker's [sic] from our key academic accounts. . . . I feel that by having young attending physicians from each of the major cancer centers[,] we will help strengthen long-term relationships between the account, the [doctor,] and Aventis Oncology. It will also . . . help generate referrals from the community.

*Id.* at 11.

Furthermore, the evidence suggests that Aventis spent millions of dollars to "develop[]" doctors into speakers in exchange for minimal work from the doctor-speakers. Relator Ex. 41 pt. 1, at 4. Aventis budgeted over $3 million for speaker programs in one year and hosted speaker "training" programs that cost more than $5000 per doctor. Ex. 53, at 23, 26; Relator Ex. 49. In exchange, the majority of Aventis speakers only completed one speaking engagement. Relator Ex. 190. In 2000, Aventis paid its most prolific speaker $70,000 in honoraria for completing thirty-five speaking engagements that year. *Id.* As such, a reasonable jury could conclude that one purpose of the speaker programs was to induce the speaker-doctors to prescribe more Taxotere.

***iii. AKS Scienter***

There is a genuine dispute of material fact about the third and final element of the AKS: whether Aventis possessed the requisite scienter. For AKS scienter, Gohil must show that Aventis knew that its speaker programs were illegal. *See Goldman*, 607 F. App'x at 174-75. Viewed in the light most favorable to Gohil, the evidence suggests: As early as 1994, Aventis knew that its speaker programs implicated the AKS because the OIG's 1994 Special Fraud Alert

warned against compensating doctors for "performing marketing tasks" including "sales-oriented 'educational'" contacts. 59 Fed. Reg. at 65,376. Aventis's internal compliance guidelines confirmed this understanding. *E.g.*, Aventis 1997 Policies, at 2-3 (referencing potential AKS liability for speaking arrangements); *id.* (prohibiting an arrangement that "does not result in a work product that provides some articulable benefit to [Aventis]" or that is "justified as necessary to build a relationship with an important customer or one whose business [Aventis] would like to expand"). Aventis managers and employees ignored the compliance guidelines about speaker programs by spending millions on speaker training in return for minimal work from speakers and by selecting doctors from "key" accounts to be speakers. *See* Relator Ex. 53, at 23, 26 (budgeting over $3 million in 1999 for speaker programs); Relator Ex. 190 (majority of speakers completed one speaking engagement in 2000); Relator Ex. 41 pt. 1, at 4, 11 (stating that Aventis needed to "increase the number of Taxotere Speaker's [sic] from our key academic accounts" to "help generate referrals from the community"). Finally, Aventis did not meaningfully discipline employees for violations of the compliance guidelines. *Supra* pp. 26-27. Thus, a reasonable jury could find that Aventis possessed AKS scienter.

Because a reasonable jury could find that Aventis violated the AKS, Gohil has raised a genuine dispute of material fact as to falsity, the first element of the FCA.

**2. Causation**

Gohil has produced sufficient evidence to show causation, the second element of an FCA violation. Gohil must prove that Aventis caused "at least one" claim to be submitted to the federal government that "sought reimbursement for medical care that was provided in violation of the Anti-Kickback Statute." *Greenfield*, 880 F.3d at 98. A reasonable jury could credit Gohil's expert and find that a kickback influences prescribing behavior for up to two years. *See* Relator

Ex. 97, at 12. So, claims submitted within that two-year window involve patients who were "exposed to an illegal recommendation or referral." *See Greenfield*, 880 F.3d at 100. For example, Aventis paid Dr. Kosty to speak at thirty-three programs in 2000, with an honorarium of $1500 per program, and at thirty-six programs in 2003, with an honorarium of $2000 per program—totaling $121,500 in speaker fees from those years. Relator Ex. 190, at 2; Relator Ex. 164 pt. 2, at 4-5. From September 21, 2000 to October 15, 2003, Dr. Kosty submitted 447 claims for Taxotere. Relator Ex. 47 app. tbl.A10, l. 170. These claims show that Dr. Kosty prescribed Taxotere within two years of his speaking engagements—the window during which Gohil's expert opines that kickbacks influence prescribing behavior. Thus, Gohil has created a genuine dispute of material fact regarding causation, the second element of the FCA.

**3. FCA Scienter**

Gohil has produced sufficient evidence to show scienter, the third element of an FCA violation. As discussed above, FCA scienter is less demanding than AKS scienter: where the FCA only requires recklessness or deliberate ignorance of illegality, the AKS requires knowledge of illegality. *Supra* p. 17. Because Gohil can survive summary judgment on AKS scienter, he can also survive summary judgment on FCA scienter.

**4. Materiality**

Gohil has produced sufficient evidence to show materiality, the fourth and final element of an FCA violation. "Material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Spay*, 875 F.3d at 746 (internal quotation marks omitted). "Materiality look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Escobar*, 136 S. Ct. at 2002 (internal quotation marks omitted).

As discussed above, Gohil has offered sufficient evidence for a reasonable jury to find that the government would not have paid for Taxotere had it known that Aventis was violating the AKS. Thus, Gohil has satisfied materiality, the fourth and final element of the FCA.

Because a reasonable jury could find for Gohil on each element of the FCA, I will deny summary judgment as to the Speaker Programs Scheme.

### C. Education Grants

Gohil has produced sufficient evidence to survive summary judgment on his claim that the Education Grants Scheme violated the FCA.

Gohil alleges that Aventis based its funding decisions for education grants on prescribing behavior. He also claims that Aventis controlled the content of the educational programs it funded. Aventis argues that its education grants were administered according to its internal guidelines as well as industry standards.

Gohil can survive summary judgment on the Education Grants Scheme because he has raised a genuine dispute of material fact as to each element of the FCA: (1) falsity (based on an AKS violation); (2) causation; (3) scienter; and (4) materiality.

#### 1. Falsity

Gohil has produced sufficient evidence to show falsity, the first element of an FCA violation. Gohil alleges that Aventis caused the submission of "legally false" claims because the claims were tainted by kickbacks. Claims that are tainted by kickbacks violate the AKS and are therefore automatically false. *Greenfield*, 880 F.3d at 94. To establish an AKS violation, Gohil must show (i) Aventis's education grants involved paying "remuneration"; (ii) at least one purpose of the education grants was to "induce" doctors to prescribe more Taxotere; and (iii) Aventis had the requisite scienter for the AKS. *See* 42 U.S.C. § 1320a-7b(b).

***i. Remuneration***

There is a genuine dispute of material fact about the first element of the AKS: whether the education grants involved paying "remuneration." A jury could find that the grants involved "transfers of items or services for free or for other than fair market value." 42 U.S.C. § 1320a-7a(i)(6). The 1994 Special Fraud Alert warned that payments—including those in the form of grants—could implicate the AKS when they were "made to a person in a position to generate business for the paying party"; "related to the volume of business generated"; and exceeded fair market value or were unrelated to services other than providing referrals. 59 Fed. Reg. at 65,376. The 2003 OIG Guidance clarified: "When evaluating educational or research grants provided by manufacturers to physicians, manufacturers should determine if the funding is based, in any way, expressly or implicitly, on the physician's referral of the manufacturer's product. If so, the funding plainly implicates the anti-kickback statute." 68 Fed. Reg. at 23,738.

Gohil has produced compelling evidence that the education grants were "remuneration" because they were allocated based on "the volume of business generated." *See* 1994 Special Fraud Alert, 59 Fed. Reg. at 65,376; *accord* 2003 OIG Guidance, 68 Fed. Reg. at 23,738. As one regional director explained: "the majority of grants should be limited to those accounts that we have access to and are using our products. I see an educational grant as a thank you for support and more for maintaining sales then [sic] increasing them." Relator Ex. 63, at 17. Before approving a grant, managers were told to consider factors including

> How much money have we given to this account in the past year? How have sales been in the past year? How important is this account to our business? Why do we want to support this particular grant/program? What will we get from supporting this program/grant? How can we track our return on investment?

*Id.* Thus, a reasonable jury could find that the education grants were remuneration.

***ii. "One Purpose to Induce"***

There is a genuine dispute of material fact about the second element of the AKS: whether one purpose of the education grants was to induce doctors to prescribe Taxotere. As one regional director explained, grants were seen as a "thank you for support and . . . for maintaining sales" and were allocated based on factors like: "How much money have we given to this account in the past year? How have sales been in the past year? How important is this account to our business?" Relator Ex. 63, at 17. One grant recipient expressed concern about an Aventis Professional Oncology Education Manager's

> not so subtle desire to turn our meeting . . . into a 2 day sales pitch for [T]axotere. She has strongly suggested for us to invite only speakers from Aventis' speakers bureau, and has implied that future funding may be compromised if this isn't done. . . . Such a biased (sales oriented) meeting certainly would compromise our academic integrity and cheapen the position that Aventis has worked to attain in GU oncology.

Relator Ex. 90. As such, a reasonable jury could conclude that one purpose of the education grants was to induce Taxotere prescription.

***iii. AKS Scienter***

There is a genuine dispute of material fact about the third and final element of the AKS: whether Aventis possessed the requisite scienter. For AKS scienter, Gohil must show that Aventis knew that its education grants were illegal. *See Goldman*, 607 F. App'x at 174-75. Viewed in the light most favorable to Gohil, the evidence suggests: As early as 1994, Aventis knew that its education grants were illegal because the OIG's 1994 Special Fraud Alert warned against payments based on the volume of business generated by the payee and specifically indicated that certain types of grants implicated the AKS. 59 Fed. Reg. at 65,376. Aventis's internal compliance guidelines confirmed this understanding. *E.g.*, Aventis 1997 Policies, at 2 (referencing potential AKS liability for interactions with individuals who purchase or have influence over the purchase of Aventis products); *id.* at 15-16 (stating that education grants could

not be allocated based on the volume of business generated by the recipient). Aventis managers and employees ignored the compliance guidelines by considering the volume of business generated by a given account when awarding education grants. *See* Relator Ex. 63, at 17 (directing managers to consider factors including: "How have sales been in the past year? How important is this account to our business?"). Finally, Aventis did not meaningfully discipline employees for violations of the compliance guidelines. *Supra* pp. 26-27. Thus, a reasonable jury could find that Aventis possessed AKS scienter.

Because a reasonable jury could find that Aventis violated the AKS, Gohil has raised a genuine dispute of material fact as to falsity, the first element of the FCA.

**2. Causation**

Gohil has produced sufficient evidence to show causation, the second element of an FCA violation. Gohil must prove that Aventis caused "at least one" claim to be submitted to the federal government that "sought reimbursement for medical care that was provided in violation of the Anti-Kickback Statute." *Greenfield*, 880 F.3d at 98. A reasonable jury could credit Gohil's expert and find that a kickback influences prescribing behavior for up to two years. *See* Relator Ex. 97, at 12. So, claims submitted within that two-year window involve patients who were "exposed to an illegal recommendation or referral." *See Greenfield*, 880 F.3d at 100. For example, on March 5, 2000, Aventis awarded a $30,000 "unrestricted educational grant" to the Prostate Cancer Research Institute ("PCRI") to "underwrite the cost of the PCRI National Conference 2000." Relator Ex. 129, at 5. Dr. Scholz was a co-founder of PCRI and sat on its board of directors in 2000. *Id.* at 6. From June 21, 2001 to December 20, 2001, Dr. Scholz submitted three claims for Taxotere. Relator Ex. 47 app. tbl.A10, l. 158. These claims show that Dr. Scholz prescribed Taxotere within two years of receiving an education grant—the window

during which Gohil's expert opines that kickbacks influence prescribing behavior. Thus, Gohil has created a genuine dispute of material fact regarding causation, the second element of the FCA.

**3. FCA Scienter**

Gohil has produced sufficient evidence to show scienter, the third element of an FCA violation. As discussed above, FCA scienter is less demanding than AKS scienter: where the FCA only requires recklessness or deliberate ignorance of illegality, the AKS requires knowledge of illegality. *Supra* p. 17. Because Gohil can survive summary judgment on AKS scienter, he can also survive summary judgment on FCA scienter.

**4. Materiality**

Gohil has produced sufficient evidence to show materiality, the fourth and final element of an FCA violation. "Material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Spay*, 875 F.3d at 746 (internal quotation marks omitted). "Materiality look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Escobar*, 136 S. Ct. at 2002 (internal quotation marks omitted).

As discussed above, Gohil has offered sufficient evidence for a reasonable jury to find that the government would not have paid for Taxotere had it known that Aventis was violating the AKS. Thus, Gohil has satisfied materiality, the fourth and final element of the FCA.

Because a reasonable jury could find for Gohil on each element of the FCA, I will deny summary judgment as to the Education Grants Scheme.

**D. <u>Preceptorships</u>**

Gohil has failed to produce sufficient evidence to survive summary judgment on his

claim that the Preceptorships Scheme violated the FCA.

As part of the preceptorship program, Aventis sales representatives shadowed doctors. Gohil alleges that Aventis scheduled preceptorships with low-prescribing doctors to convince doctors to increase their Taxotere usage. Aventis claims that it conducted preceptorships in accordance with internal compliance guidelines—which prohibited promotional activity during preceptorships—and that its preceptorships conformed with industry standards.

Gohil cannot survive summary judgment on the Preceptorships Scheme because he has not created a genuine dispute of material fact as to each element of the FCA. To establish an FCA violation, Gohil must show (1) falsity (based on an AKS violation); (2) causation; (3) scienter; and (4) materiality. The evidence—even when viewed in the light most favorable to Gohil—does not show causation, the second element of the FCA. Gohil has failed to show that Aventis caused "at least one" claim to be submitted to the federal government that "sought reimbursement for medical care that was provided in violation of the Anti-Kickback Statute," which would make the claim false. *Greenfield*, 880 F.3d at 98.

Gohil only submits evidence regarding two doctors—Dr. Vicario and Dr. Moskowitz—who allegedly participated in Aventis's preceptorship program and subsequently submitted claims. Relator Causation Chart 5. A reasonable jury could credit Gohil's expert and find that a kickback influences prescribing behavior for up to two years. *See* Relator Ex. 97, at 12. So, claims submitted within that two-year window involve patients who were "exposed to an illegal recommendation or referral." *See Greenfield*, 880 F.3d at 100. Even if a jury credits Gohil's expert, Gohil has offered no evidence that a kickback affects prescribing behavior for more than two years. Thus, evidence that doctors submitted claims outside of the two-year window is insufficient to show causation.

Gohil has produced no evidence that any doctors submitted claims within two years of a preceptorship. First, Gohil offers evidence that Aventis paid Dr. Moskowitz $500 for a preceptorship that occurred on May 6, 1999. Relator Ex. 111. From January 1, 1998 (before the preceptorship occurred) to December 31, 2004 (five years after the preceptorship), Dr. Moskowitz submitted 646 claims for Taxotere. Relator Ex. 47 app. tbl.A1, l. l34. There is no evidence detailing how many claims were submitted within a given year. So, it is possible that Dr. Moskowitz submitted *no* claims within two years of the alleged kickback. In fact, Dr. Moskowitz may have submitted most or even all of his 646 claims between January 1, 1998 and May 5, 1999, before the preceptorship even occurred.

Next, Gohil offers evidence that an Aventis sale representative stated in her 1998 Business Plan: "Vicario is very profit oriented, and [is] interested in a business relationship with [Aventis]. I have some preceptorships scheduled with [him]." Relator Ex. 25, at 10. From July 31, 2003 (five years after the preceptorship) to January 30, 2004 (six years after the preceptorship), Dr. Vicario submitted sixty-one claims for Taxotere. Relator Ex. 47 app. tbl.A10, l. 41. Assuming the preceptorship occurred as scheduled in 1998, there is no evidence that Dr. Vicario submitted any claims within two years of the preceptorship. As such, Gohil has not shown that Dr. Vicario prescribed Taxotere within two years of the alleged kickback—the window during which Gohil's expert opines that a kickback influences prescribing behavior. Thus, Gohil has not sufficiently shown causation.

Because Gohil has not produced evidence to show that each element of the FCA is met, I will grant summary judgment as to the Preceptorships Scheme.

**E. Ad Hoc Kickbacks**

Gohil has only produced sufficient evidence to survive summary judgment on his claim

that Aventis's provision of meals and gift baskets violated the FCA. He has failed to produce sufficient evidence for the remaining alleged ad hoc kickbacks and therefore cannot survive summary judgment on them.

In addition to formal schemes, Gohil alleges that Aventis provided a variety of ad hoc kickbacks to increase sales: Aventis sent gift baskets, took doctors out for meals, and provided other valuable gifts and entertainment. Aventis argues that its sales tactics complied with internal guidelines and industry standards.

Because Gohil alleges a wide variety of ad hoc kickbacks, he must show that each *type* of kickback meets the FCA requirements of (1) falsity (based on an AKS violation); (2) causation; (3) scienter; and (4) materiality. Gohil has only met his burden for summary judgment for Aventis's provision of meals and gift baskets because he has produced evidence of causation only for these two types of ad hoc kickbacks. Gohil was on notice that he needed to show causation for each type of ad hoc kickback: "Relator must err on the side of specificity. The various 'ad hoc' kickbacks Relator describes are not identical, and proof of a [causal] 'link' for one type (e.g., baseball tickets) may not necessarily mean proof of a 'link' exists for another type (e.g., expensive dinners or private parties)." Causation Briefing Order at 2 n.1. Yet, Gohil only discussed meals and gift baskets in his causation briefing. *See* Relator Causation Chart 7. Because Gohil failed to show that each element of the FCA is met for the remaining alleged ad hoc kickbacks, I will grant summary judgment on all ad hoc kickbacks other than Aventis's provision of meals and gift baskets.

I will discuss Aventis's provision of meals and gift baskets below.

**1. Falsity**

Gohil has produced sufficient evidence to show falsity, the first element of an FCA

violation. Gohil alleges that Aventis caused the submission of "legally false" claims because the claims were tainted by kickbacks. Claims that are tainted by kickbacks violate the AKS and are therefore automatically false. *Greenfield*, 880 F.3d at 94. To establish an AKS violation, Gohil must show (i) Aventis's provision of meals and gift baskets involved paying "remuneration"; (ii) at least one purpose of the meals and gift baskets was to "induce" doctors to prescribe more Taxotere; and (iii) Aventis had the requisite scienter for the AKS. *See* 42 U.S.C. § 1320a-7b(b).

***i. Remuneration***

There is a genuine dispute of material fact about the first element of the AKS: whether the provision meals and gift baskets involved paying "remuneration." A jury could find that Aventis provided "transfers of items or services for free or for other than fair market value." 42 U.S.C. § 1320a-7a(i)(6). The OIG's 1994 Special Fraud Alert listed as a potential AKS violation

> [a]ny prize, gift or cash payment, coupon or bonus (e.g., airline discounts and related travel premiums), offered to physicians and/or suppliers . . . in exchange for, or based on, prescribing or providing specific prescription products. These items are particularly suspect if based on value or volume of business generated for the drug company.

59 Fed. Reg. at 65,376. Likewise, the 2003 OIG Guidance stated:

> Examples of remunerative arrangements between pharmaceutical manufacturers (or their representatives) and parties in a position to influence referrals include: [e]ntertainment, recreation, travel, meals, or other benefits in association with information or marketing presentations; and [g]ifts, gratuities, and other business courtesies. As discussed above, these arrangements potentially implicate the anti-kickback statute if any one purpose of the arrangement is to generate business for the pharmaceutical company.

68 Fed. Reg. at 23,738.

A reasonable jury could find that Aventis's provision of meals and gift baskets involved paying remuneration because they were "based on value or volume of business generated" by the recipient. *See* 1994 Special Fraud Alert, 59 Fed. Reg. at 65,376. For example, one area manager

praised a sales team that "took a very important account of theirs out to dinner" because doing so "opens the doors for future access [and] gives us the ability to do the things that we need to do to impact the business." Relator Ex. 33, at 25 (Ex. F.). Likewise, a jury could find that Aventis's provision of gift baskets to "Taxotere Speakers" (Aventis-trained doctors who completed speaking engagements about Taxotere) were "benefits in association with information or marketing presentations." Relator Ex. 188; *see* 2003 OIG Guidance, 68 Fed. Reg. at 23,738. Thus, there is a genuine dispute of material fact as to whether Aventis's provision of meals and gift baskets involved paying remuneration in violation of the AKS.

***ii. "One Purpose to Induce"***

There is a genuine dispute of material fact about the second element of the AKS: whether one purpose of the meals and gift baskets was to induce doctors to prescribe Taxotere. In a 2001 business plan, two sales team members listed a series of dinners in their promotional budget. Relator Ex. 55 pt. 1, at 4, 5. The "expected return" from the dinner events was "[i]ncrease[d] Taxotere usage." *Id.* Similarly, the sales team listed as promotional ideas: "Gifts [for] attainment of certain volume business [and] gift certificates." *Id.* As such, a reasonable jury could conclude that one purpose of Aventis's provision of meals and gift baskets was to induce Taxotere prescription.

***iii. AKS Scienter***

There is a genuine dispute of material fact about the third and final element of the AKS: whether Aventis possessed the requisite scienter. For AKS scienter, Gohil must show that Aventis knew that its meals and gift baskets were illegal. *See Goldman*, 607 F. App'x at 174-75. Viewed in the light most favorable to Gohil, the evidence suggests: As early as 1994, Aventis knew that its meals and gift baskets were illegal because the OIG's 1994 Special Fraud Alert

warned against gifts and payments that were based on the volume of business generated by the payee or offered in exchange for prescribing certain products. 59 Fed. Reg. at 65,376. Aventis's internal compliance guidelines confirmed this understanding. *E.g.*, Aventis 1997 Policies, at 2 (referencing potential AKS liability for interactions with individuals who purchase or have influence over the purchase of Aventis products); *id.* at 25-29 (stating that gifts and business courtesies could not be "given in exchange for an explicit or implicit agreement to purchase or recommend [Aventis] products"). Aventis managers and employees ignored the compliance guidelines by providing meals based on the volume of business generated by a client and by sending gift baskets to doctors who completed speaking engagements recommending Taxotere to their peers. *See* Relator Ex. 33, at 25-26 (Ex. F) (applauding a sales team that "took a very important account of theirs out to dinner"); Relator Ex. 188 (sending gift baskets to "Taxotere Speakers"). Finally, Aventis did not meaningfully discipline employees for violations of the compliance guidelines. *Supra* pp. 26-27. Thus, a reasonable jury could find that Aventis possessed AKS scienter.

Because a reasonable jury could find that Aventis violated the AKS, Gohil has raised a genuine dispute of material fact as to falsity, the first element of the FCA.

**2. Causation**

Gohil has produced sufficient evidence to show causation, the second element of an FCA violation. Gohil must prove that Aventis caused "at least one" claim to be submitted to the federal government that "sought reimbursement for medical care that was provided in violation of the Anti-Kickback Statute." *Greenfield*, 880 F.3d at 98. A reasonable jury could credit Gohil's expert and find that a kickback influences prescribing behavior for up to two years. *See* Relator Ex. 97, at 12. So, claims submitted within that two-year window involve patients who were

"exposed to an illegal recommendation or referral." *See Greenfield*, 880 F.3d at 100. In 2002, a regional director took Dr. Langer out to dinner and "discussed [his institution's] low Taxotere sales and usage." Relator Ex. 41 pt. 1, at 11. From June 14, 2003 to December 13, 2003, Dr. Langer submitted twelve claims for Taxotere. Relator Ex. 47 app. tbl.A10, l. 34. Similarly, in December 1999, Aventis sent Dr. Kris a gift basket for being a "Taxotere Speaker." Relator Ex. 188, at 4. From January 1, 2000 to June 30, 2000, Dr. Kris submitted nine claims for Taxotere. Relator Ex. 47 app. tbl.A10, l. 151. These claims show that Dr. Langer and Dr. Kris prescribed Taxotere within two years of receiving meals and gift baskets—the window during which Gohil's expert opines that kickbacks influence prescribing behavior. Thus, Gohil has created a genuine dispute of material fact regarding causation, the second element of the FCA.

**3. FCA Scienter**

Gohil has produced sufficient evidence to show scienter, the third element of an FCA violation. As discussed above, FCA scienter is less demanding than AKS scienter: where the FCA only requires recklessness or deliberate ignorance of illegality, the AKS requires knowledge of illegality. *Supra* p. 17. Because Gohil can survive summary judgment on AKS scienter, he can also survive summary judgment on FCA scienter.

**4. Materiality**

Gohil has produced sufficient evidence to show materiality, the fourth and final element of an FCA violation. "Material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Spay*, 875 F.3d at 746 (internal quotation marks omitted). "Materiality look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Escobar*, 136 S. Ct. at 2002 (internal quotation marks omitted).

As discussed above, Gohil has offered sufficient evidence for a reasonable jury to find that the government would not have paid for Taxotere had it known that Aventis was violating the AKS. Thus, Gohil has satisfied materiality, the fourth and final element of the FCA.

Because a reasonable jury could find for Gohil on each element of the FCA, I will deny summary judgment as to Aventis's provision of meals and gift baskets.

## VI. CONCLUSION

For the above reasons, I will deny Aventis's motion for summary judgment on the Advisory Boards, Speaker Programs, and Education Grants schemes. I will grant the motion as to the Preceptorships and False Advertising schemes. I will deny the motion as to the meals and gift baskets aspects of the Ad Hoc Kickbacks scheme and grant the motion as to the remaining alleged ad hoc kickbacks.

Thus, the FCA claims remaining in the action are based on the following alleged kickbacks:

1. PACT Program;[14]
2. advisory boards;
3. speaker programs;
4. education grants; and
5. meals and gift baskets (originally alleged as part of the Ad Hoc Kickbacks Scheme).

s/ANITA B. BRODY, J.
ANITA B. BRODY, J.

Copies **VIA ECF 11/12/2020**

[14] On March 4, 2020, I denied cross-motions for summary judgment on the PACT program. *See generally* PACT Summ. J. Mem.